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(54) **METHODS AND APPARATUS FOR TREATING VERTEBRAL FRACTURES**

(52) **U.S. Cl. 606/92; 606/192**

(57) **ABSTRACT**

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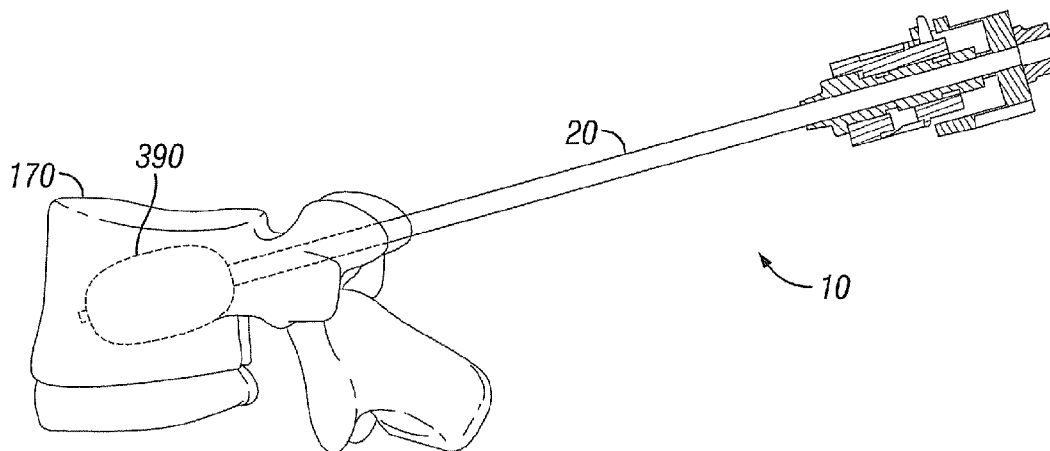
Methods and apparatus for treating bones, including, in one or more embodiments, methods and apparatus for treatment of vertebral fractures that include a containment assembly for cement containment and/or a balloon assembly for maintaining vertebral height. Methods for treating a bone comprising: inserting a cannula having an inner lumen into the bone; creating a cavity in the bone; providing a containment assembly, wherein the containment assembly may comprise a tubular member having a proximal end and a distal end, a containment jacket disposed on the distal end of the tubular member, and a guide wire disposed through the tubular member with the guide extending into the containment jacket; inserting the containment jacket through the inner lumen of the cannula and into the cavity; and introducing a filler material into the containment jacket.

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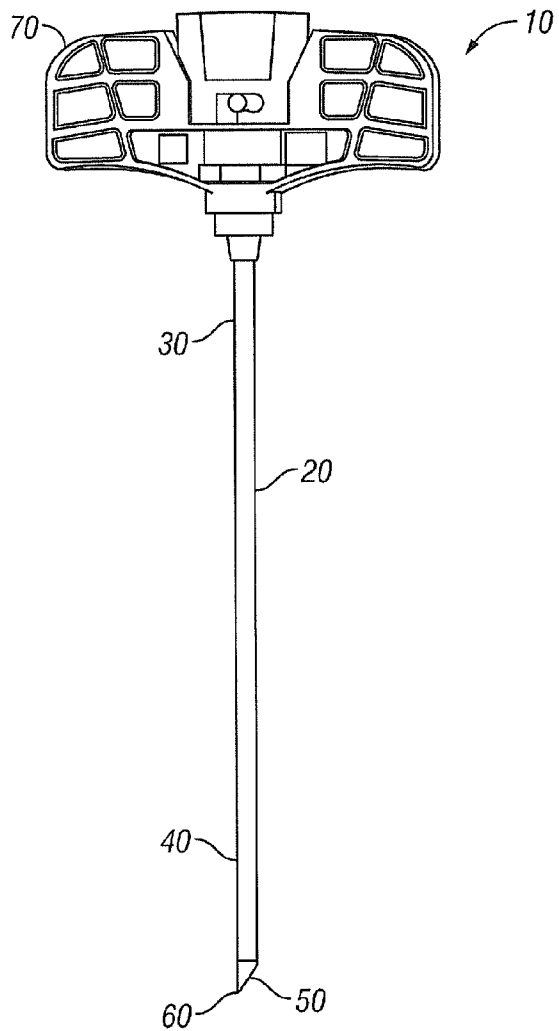


FIG. 1

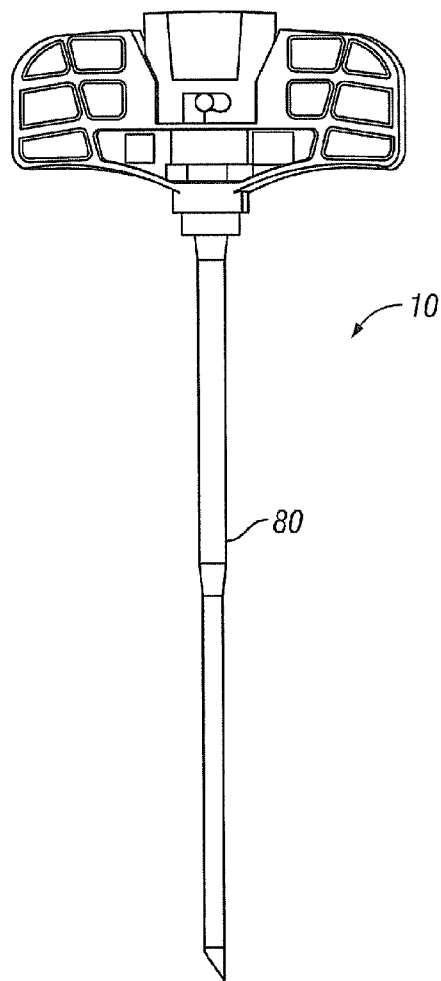


FIG. 2

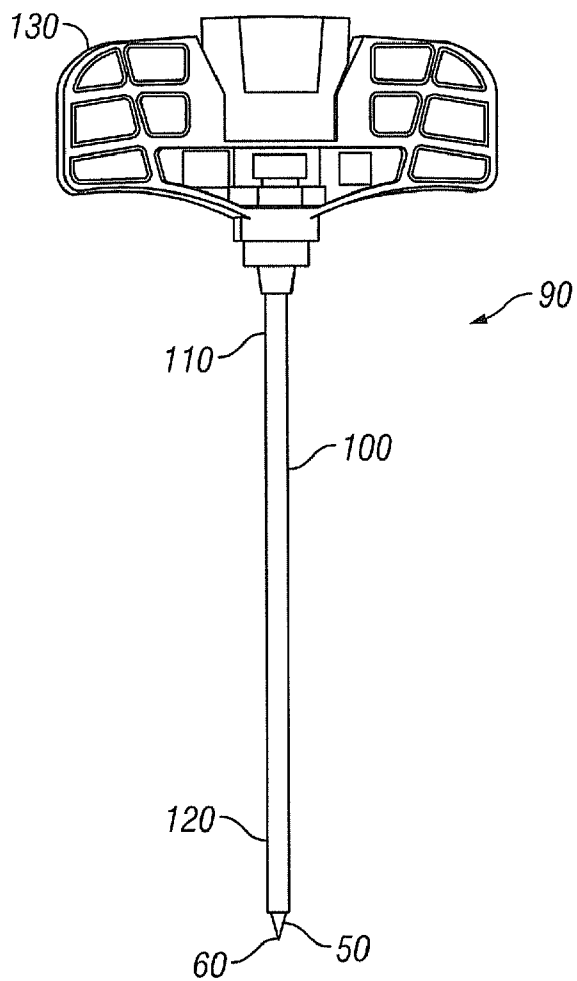


FIG. 3

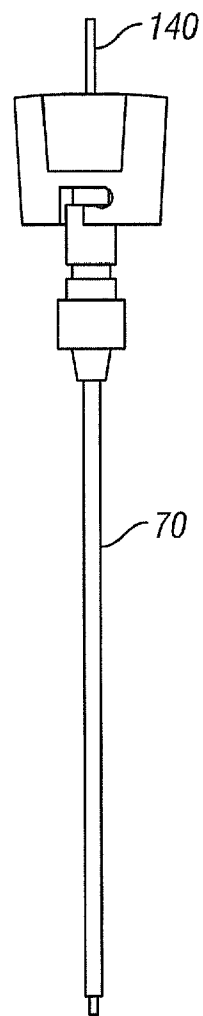


FIG. 4

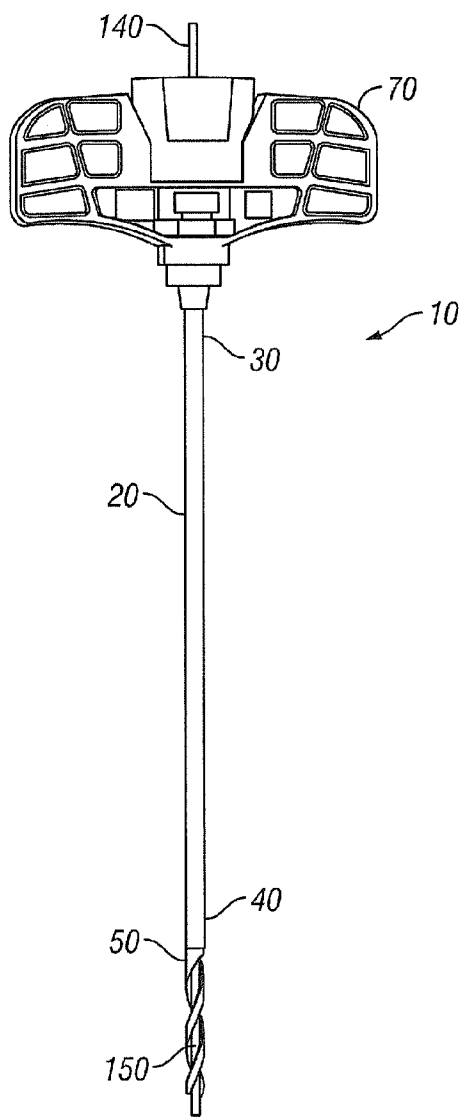


FIG. 5

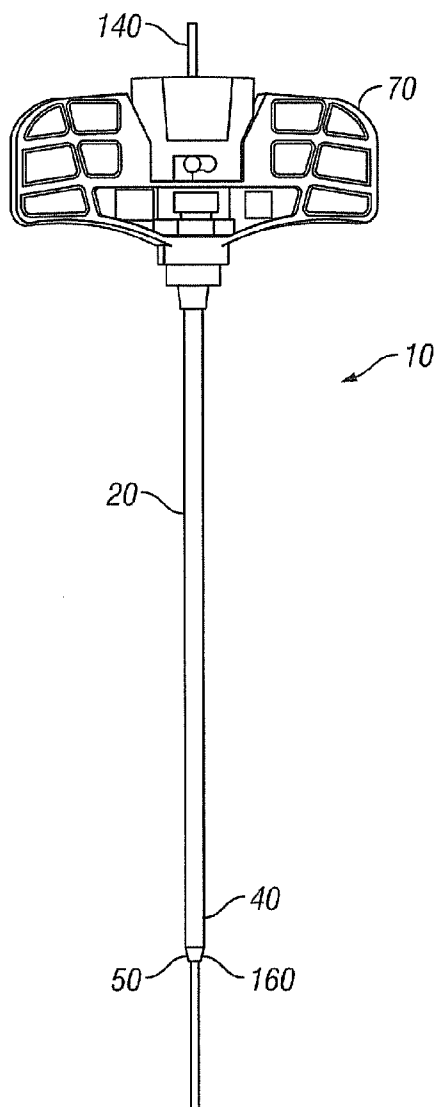
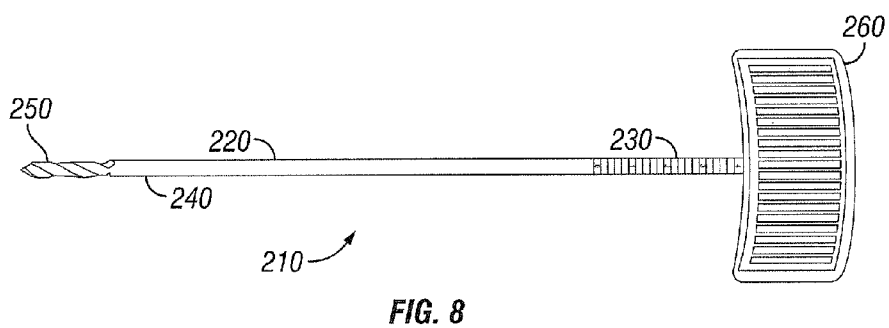
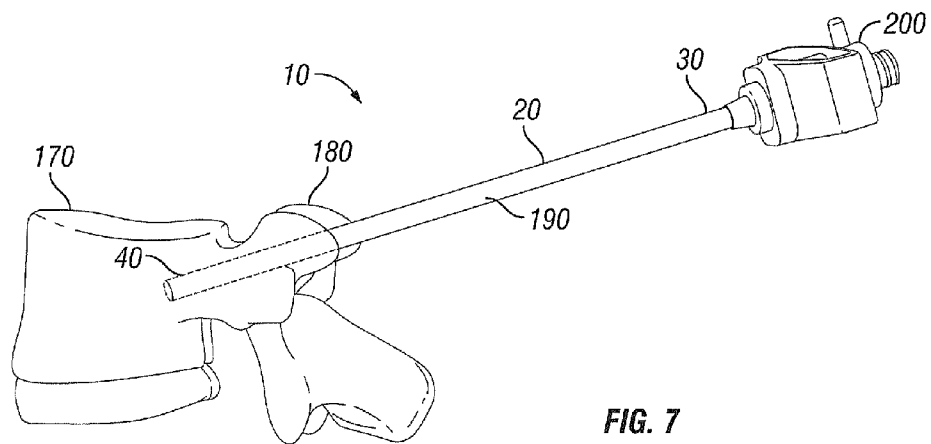


FIG. 6



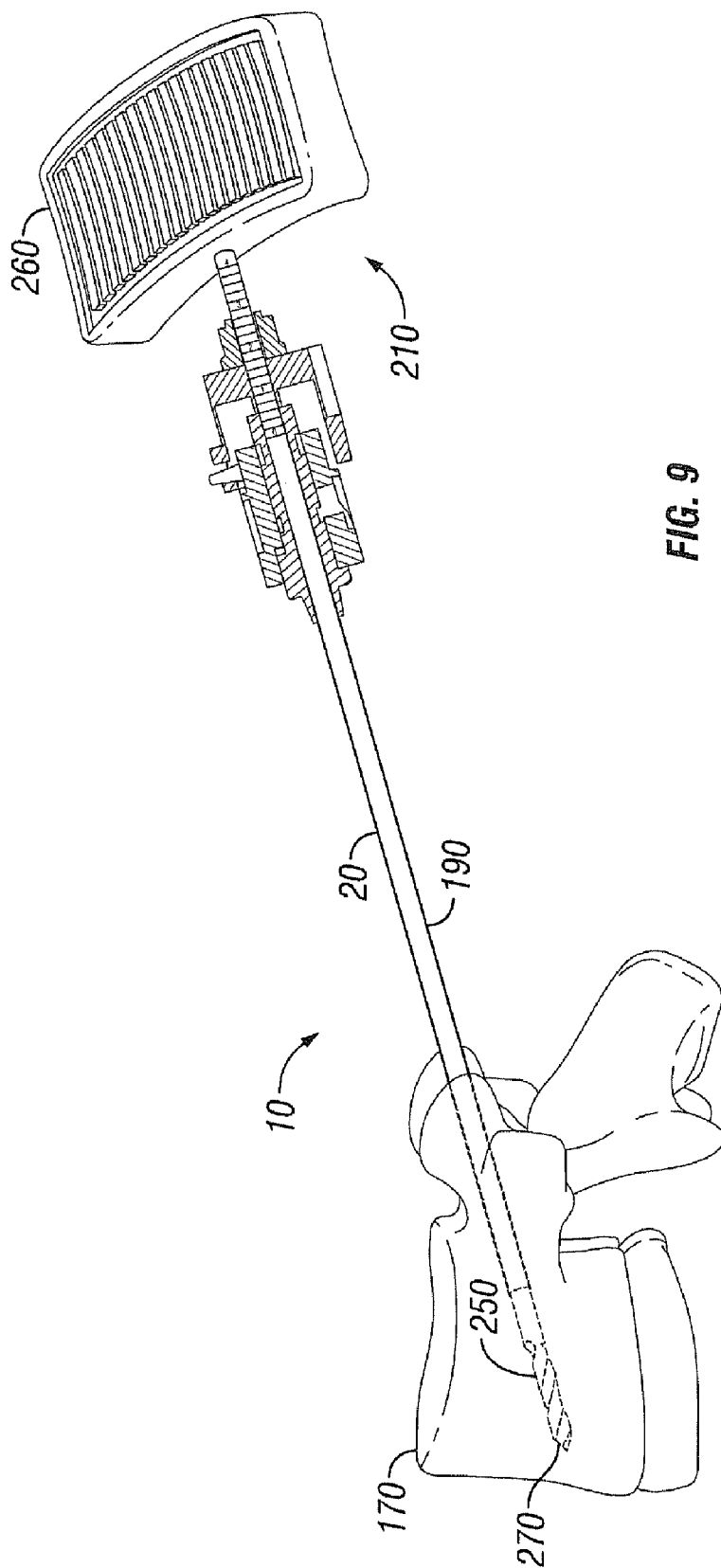
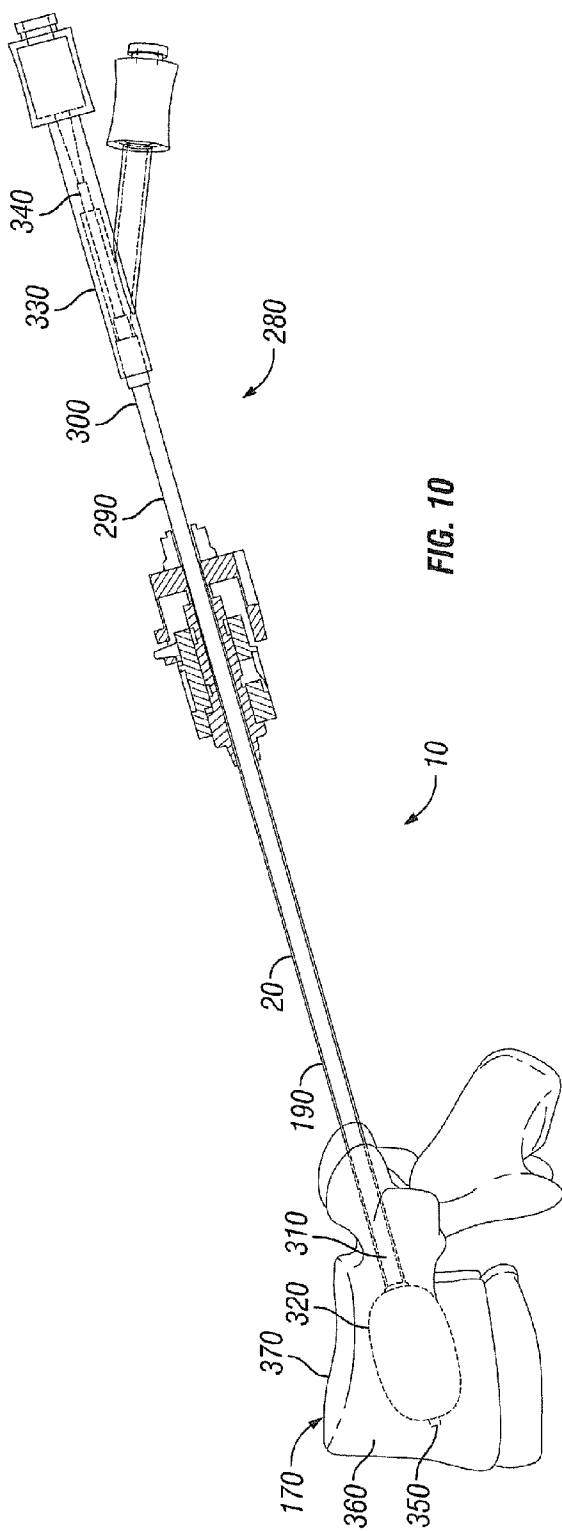


FIG. 9



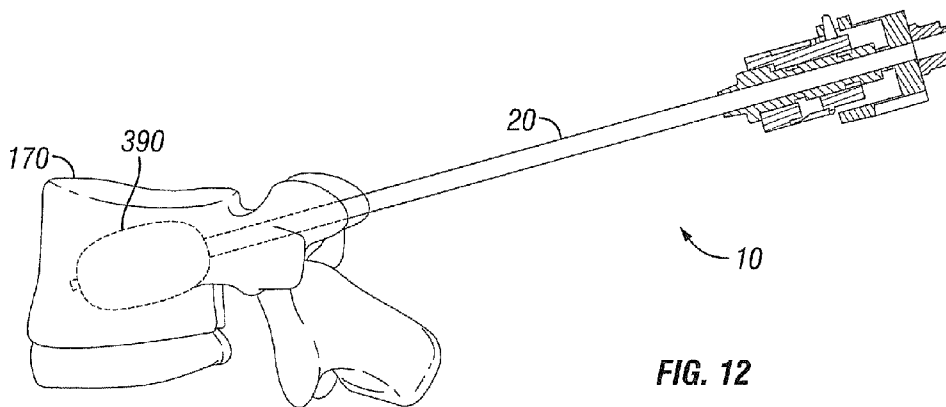


FIG. 12

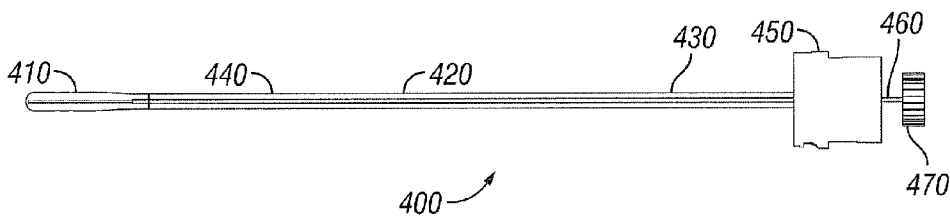


FIG. 13

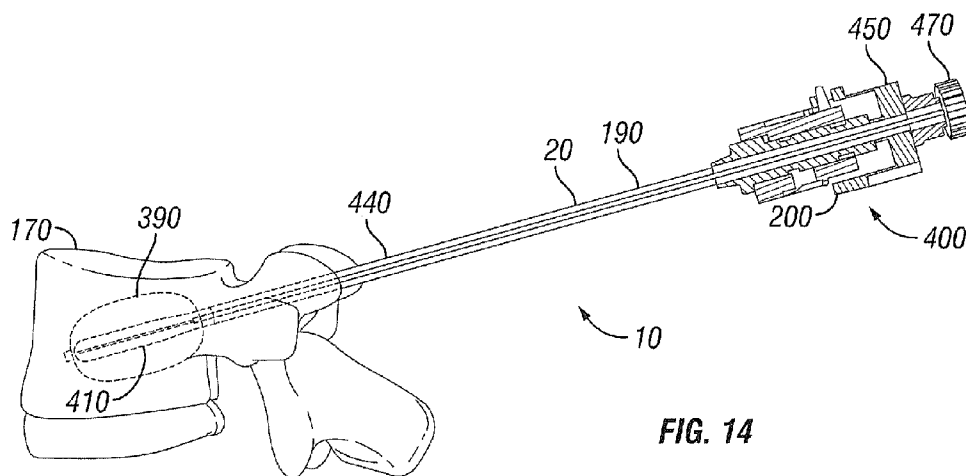


FIG. 14

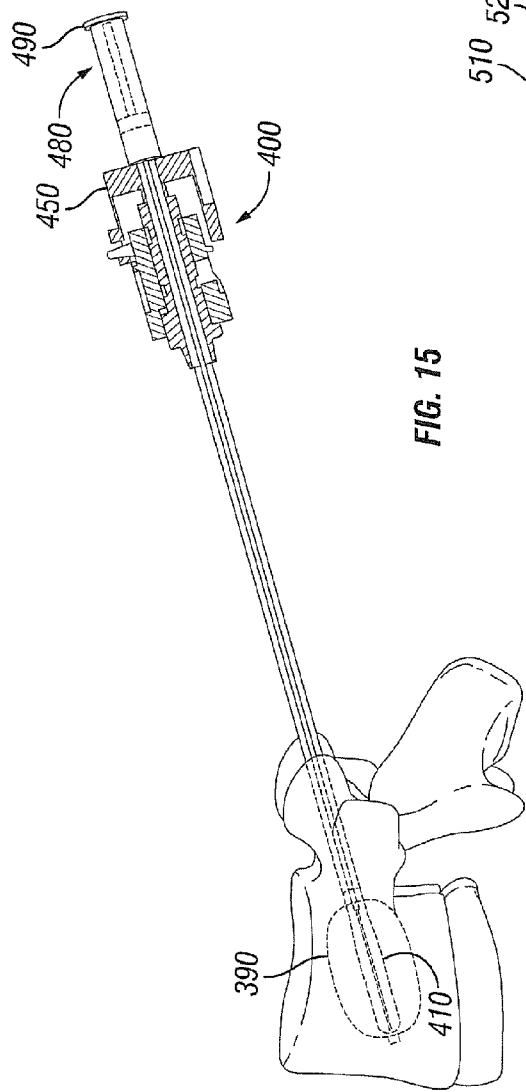


FIG. 15

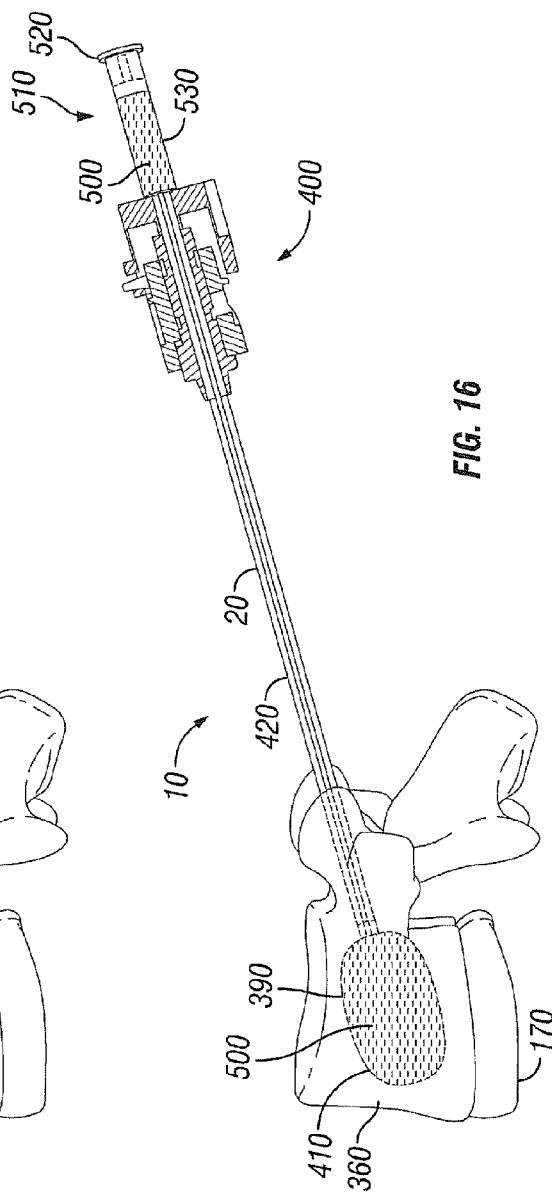


FIG. 16

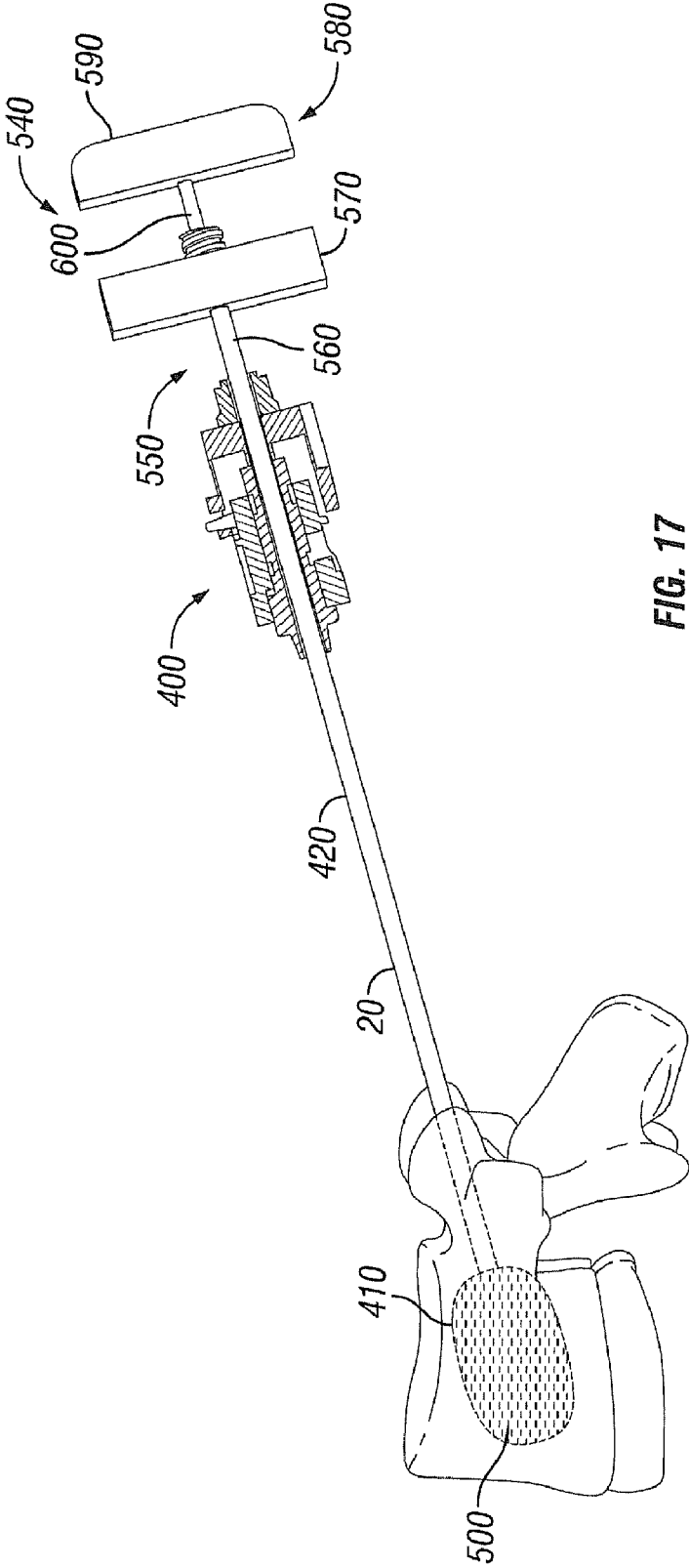


FIG. 17

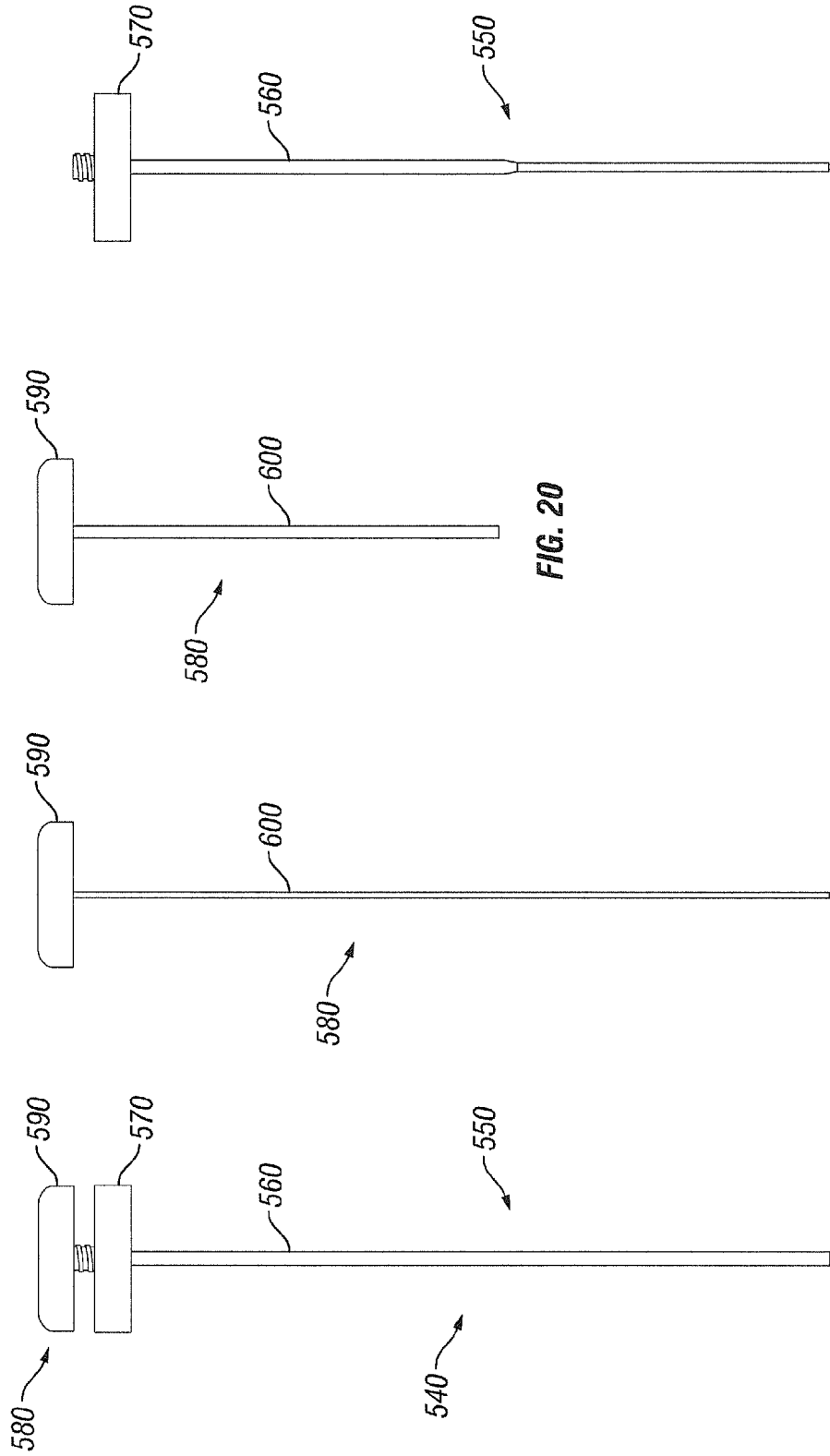
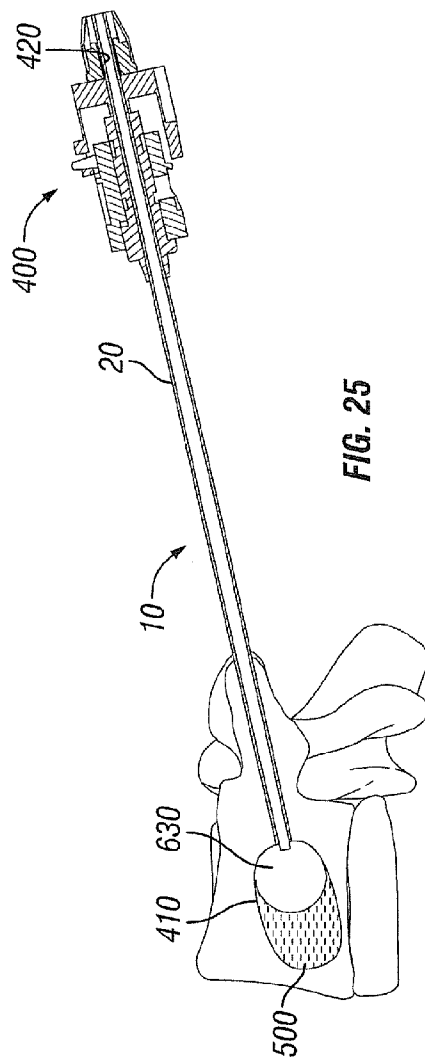
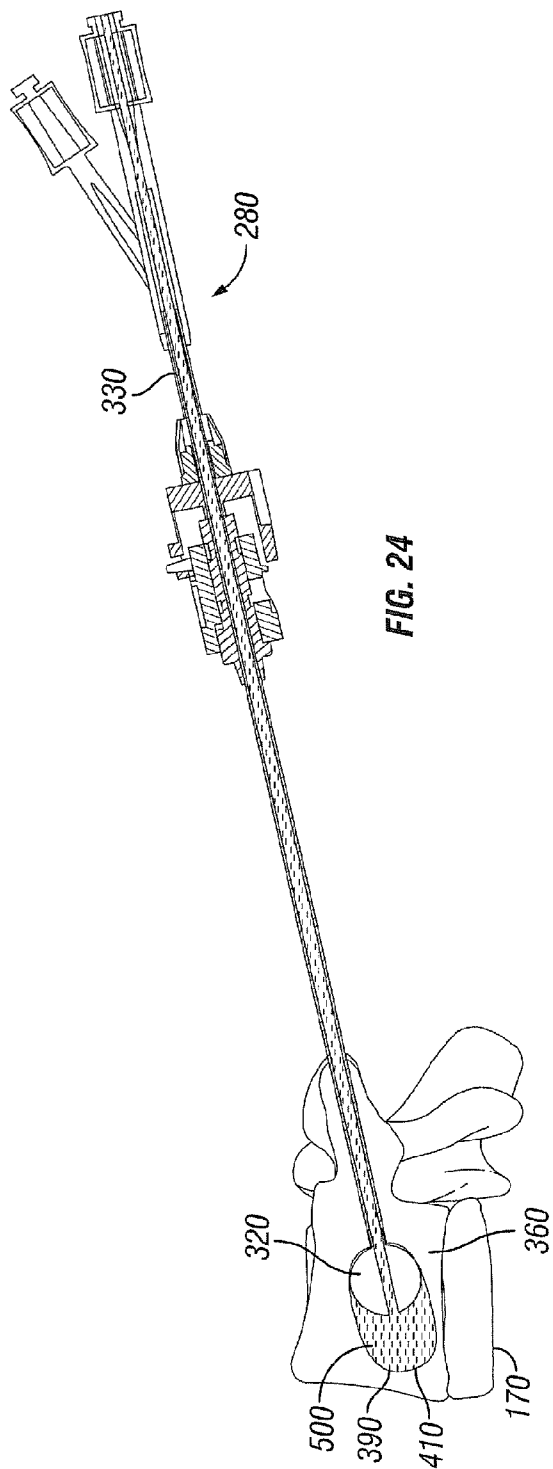


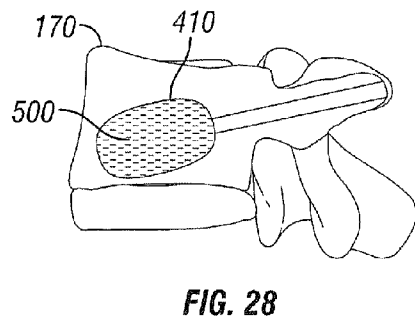
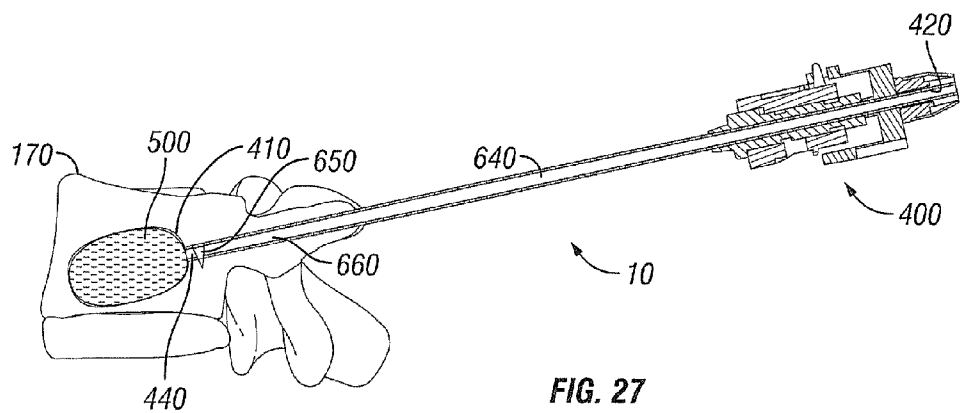
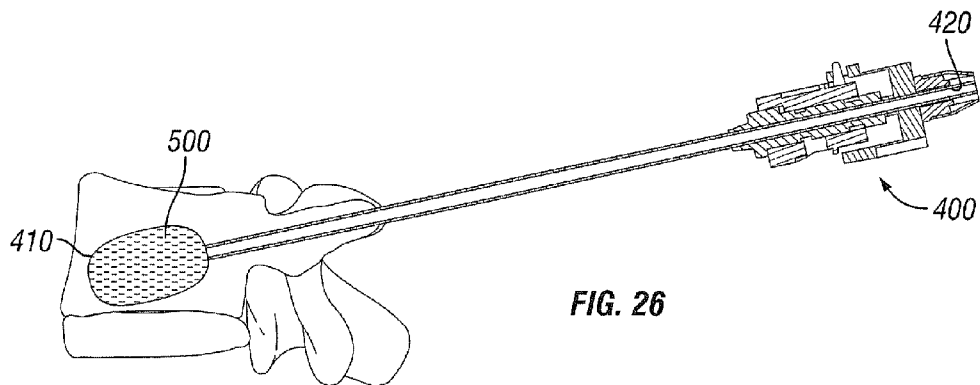
FIG. 21

FIG. 20

FIG. 19

FIG. 18





METHODS AND APPARATUS FOR TREATING VERTEBRAL FRACTURES

FIELD OF THE INVENTION

[0001] The present disclosure generally relates to treatment of bones. In particular, in one or more embodiments, the present disclosure relates to methods and apparatus for treatment of vertebral fractures that include a containment assembly for cement containment and/or a balloon assembly for maintaining vertebral height.

BACKGROUND

[0002] Bones and bony structures are susceptible to a variety of weaknesses that can affect their ability to provide support and structure. Weaknesses in bony structures may have many causes, including degenerative diseases, tumors, fractures, and dislocations. By way of example, weaknesses in vertebrae can lead to compression fractures that involve the collapse of one or more vertebrae in the spine. These vertebral compression fractures may be caused by a number of conditions including osteoporosis, trauma, and tumors. Advances in medicine and engineering have provided doctors with a plurality of devices and techniques for alleviating or curing these weaknesses.

[0003] One technique for treating vertebral fractures is vertebroplasty. In vertebroplasty, a physician may use a needle to inject bone cement into a fractured vertebral body to stabilize the fracture. Kyphoplasty is another technique for treating vertebral fractures that involves insertion of a balloon into the fractured vertebra to restore the height of the vertebra. The balloon may then be removed followed by injection of bone cement into the vertebral body to stabilize the fracture. Leakage of the bone cement in both vertebroplasty and kyphoplasty is a common problem that can lead to complications. Another problem associated with these techniques is the potential for inadequate height restoration to the fractured vertebral body.

[0004] Thus, there is a need for methods and apparatus that can provide stabilization to a fractured vertebra.

SUMMARY

[0005] The present disclosure generally relates to treatment of bones. In particular, in one or more embodiments, the present disclosure relates to methods and apparatus for treatment of vertebral fractures that include a containment assembly for cement containment and/or a balloon assembly for maintaining vertebral height.

[0006] An embodiment includes a method for treating a bone. The method may comprise inserting a cannula having an inner lumen into the bone. The method may further comprise creating a cavity in the bone. The method may further comprise providing a containment assembly. The containment assembly may comprise a tubular member having a proximal end and a distal end. The containment assembly may further comprise a containment jacket disposed on the distal end of the tubular member. The containment assembly may further comprise a guide wire disposed through the tubular member with the guide extending into the containment jacket. The method may further comprise inserting the containment jacket through the inner lumen of the cannula and into the cavity. The method may further comprise introducing a filler material into the containment jacket.

[0007] The features and advantages of the present invention will be readily apparent to those skilled in the art. While numerous changes may be made by those skilled in the art, such changes are within the spirit of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] These drawings illustrate certain aspects of the present invention and should not be used to limit or define the invention.

[0009] FIG. 1 illustrates a cannula assembly in accordance with one embodiment of the present technique.

[0010] FIG. 2 illustrates a cannula assembly having a tapered cannula in accordance with one embodiment of the present invention.

[0011] FIG. 3 illustrates a needle assembly in accordance with one embodiment of the present invention.

[0012] FIG. 4 illustrates a needle assembly having a guide wire disposed therethrough in accordance with one embodiment of the present invention.

[0013] FIG. 5 illustrates a cannula assembly disposed over a guide wire and having a drill-tip stylet in accordance with one embodiment of the present invention.

[0014] FIG. 6 illustrates a cannula assembly disposed over a guide wire and having a conical-tip stylet in accordance with one embodiment of the present invention.

[0015] FIG. 7 illustrates a cannula assembly inserted into a vertebral body in accordance with one embodiment of the present invention.

[0016] FIG. 8 illustrates a drill that can be used in accordance with one embodiment of the present invention.

[0017] FIG. 9 illustrates insertion of a drill through the cannula assembly to create a channel in a vertebral body in accordance with one embodiment of the present invention.

[0018] FIG. 10 illustrates insertion of a balloon into a vertebral body in accordance with one embodiment of the present invention.

[0019] FIG. 11 illustrates a mechanical device that can be used to create a cavity in a vertebral body in accordance with one embodiment of the present invention.

[0020] FIG. 12 illustrates a cavity in a vertebral body in accordance with one embodiment of the present invention.

[0021] FIG. 13 illustrates a containment assembly in accordance with one embodiment of the present invention.

[0022] FIG. 14 illustrates insertion of a containment assembly into a vertebral body in accordance with one embodiment of the present invention.

[0023] FIG. 15 illustrates removal of fluid from a containment jacket placed in a vertebral body in accordance with one embodiment of the present invention.

[0024] FIG. 16 illustrates use of a syringe-type device to introduce filler material into a containment jacket placed in a vertebral body in accordance with one embodiment of the present invention.

[0025] FIG. 17 illustrates use of a needle-type device to introduce filler material into a containment jacket placed in a vertebral body in accordance with one embodiment of the present invention.

[0026] FIGS. 18-21 illustrate needle-type devices that may be used in accordance with embodiments of the present invention.

[0027] FIG. 22 illustrates insertion of a balloon into a containment jacket placed in a vertebral body in accordance with one embodiment of the present invention.

[0028] FIG. 23 illustrates inflation of a balloon in a containment jacket placed within a vertebral body in accordance with one embodiment of the present invention.

[0029] FIG. 24 illustrates introduction of a filler material into a vertebral body while using a balloon in accordance with one embodiment of the present invention.

[0030] FIG. 25 illustrates a containment jacket placed within a vertebral body that has been partially filled in accordance with one embodiment of the present invention.

[0031] FIG. 26 illustrates introduction of filler material to fill the remainder of a containment jacket placed within a vertebral body in accordance with one embodiment of the present invention.

[0032] FIG. 27 illustrates detachment of the containment jacket from a containment assembly in accordance with one embodiment of the present invention.

[0033] FIG. 28 illustrates a containment jacket placed within a vertebral body, the containment jacket containing a filler material, in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0034] Embodiments of the present technique for treating vertebral fractures may include creating an access channel into a vertebral body. FIG. 1 illustrates a cannula assembly 10 that may be used to create an access channel through a patient's tissue to a vertebral body (not illustrated) in accordance with one embodiment of the present invention. In the illustrated embodiment, the cannula assembly 10 comprises a cannula 20 configured to allow passage of various instruments and materials into the vertebral body. The cannula 20 may have a proximal end 30 and a distal end 40. The cannula assembly 10 further may include a stylet 50 removably disposed in the cannula 20. As illustrated, the stylet 50 may have a pointed end 60 that extends beyond the distal end 40 of the cannula 20. In an embodiment, the cannula assembly 10 may further comprise a handle 70 disposed on the proximal end of the cannula 20. In an embodiment, the cannula assembly 10 may be a trocar-tipped cannula. By way of example, the cannula assembly 10 may be a diamond, scoop, bevel, trocar tipped cannula.

[0035] To create the access channel, the physician may make an incision in the patient's back, for example. The distal end 40 of the cannula 20 may be inserted into the incision. The physician may then apply longitudinal force to the cannula assembly 10 while rotating the handle 70 to advance the cannula 20 through the patient's tissue and into a vertebral body. In other embodiments, the handle 70 may use other mechanisms to advance the cannula 20 through the patient's tissue, such as a ratcheting system. In an embodiment, the cannula 20 may be inserted into the vertebral body through a pedicle. Once the cannula 20 has been inserted into the vertebral body, the stylet 50 and handle 70 may be removed, leaving the cannula 20. In this manner, the cannula 20 may provide an access channel into the vertebral body.

[0036] While the cannula assembly 10 may be suited for creating an access channel to vertebral bodies in all regions of the vertebral column, the cannula assembly 10 may be particularly suited for access in the middle of the thoracic region and lower. If access is desired from the middle of the thoracic region and above, a device having a tapered cannula may be used, in accordance with one embodiment. FIG. 2 illustrates a cannula assembly 10 having a tapered cannula 80 in accordance with an embodiment of the present invention.

While the tapered cannula 80 may be particularly suited for accessing the middle of the thoracic region and above, it should be understood that the tapered cannula 80 may also be used to create an access channel to vertebral bodies in all regions of the vertebral column.

[0037] While FIG. 1-2 describe use of a cannula assembly 10 that is sharp and pointed for creating an access channel into a vertebral body, it should be understood that a variety of different devices and techniques may be used to create the access channel in accordance with embodiment of the present invention. Referring now to FIGS. 3-6, an alternative technique for creating an access channel into a vertebral body is illustrated in accordance with one embodiment of the present invention.

[0038] FIG. 3 illustrates a needle assembly 90 that may be used to create an access channel through a patient's tissue to a vertebral body (not illustrated) in accordance with an embodiment of the present invention. In the illustrated embodiment, the needle assembly 90 comprises a needle 100 having a proximal end 110 and a distal end 120. The needle assembly 90 further may include a stylet 50 removably disposed in the needle 100. As illustrated, the stylet 50 may have a pointed end 60 that extends beyond the distal end 120 of the needle 100. As illustrated, the needle assembly 90 may further comprise a handle 130 disposed on the proximal end 110 of the needle 100. In an embodiment, the needle assembly 90 is a diamond, bevel tipped Jamshidi needle.

[0039] The needle assembly 90 of FIG. 3 may be inserted into the vertebral body in a similar manner to the cannula assembly 10 of FIG. 1. By way of example, the distal end 120 of the needle 100 may be inserted into an incision in the patient's back. To advance the needle 100 into the vertebral body, longitudinal force may then be applied to the needle assembly 90 while rotating the handle 130. The stylet 50 and handle 130 may then be removed, leaving the needle 100. As illustrated by FIG. 4, a guide wire 140 (e.g., a k-wire) may be disposed through the needle 100 and into the vertebral body. With the guide wire 140 in place, the needle 100 may be removed.

[0040] As illustrated by FIG. 5, after removal of the needle 100, a cannula assembly 10 may be inserted over the guide wire 140 and into the vertebral body. In the illustrated embodiment, the cannula assembly 10 includes a cannula 20 having a handle 70 disposed on the proximal end 30. In an embodiment, a stylet 50 having a drill-shaped end 150 may be disposed in the cannula 20. As illustrated, the drill-shaped end 150 of the stylet 50 may extend out from the distal end 40 of the cannula 20. FIG. 6 illustrates an alternative embodiment of the cannula assembly 10. As illustrated by FIG. 6, the stylet 50 disposed in the cannula 20 may have a conically shaped end 160 extending out from the distal end 40 of the cannula 20. To advance the cannula assembly 10 over the guide wire 140 and through the patient's tissue, the physician may apply longitudinal force to the cannula assembly 10 while rotating the handle 70. Once the cannula assembly 10 has been inserted into the vertebral body, the stylet 50, handle 70, and guide wire 140 may be removed, leaving the cannula 20. In this manner, the cannula 20 may provide an access channel into the vertebral body.

[0041] FIG. 7 illustrates a cannula assembly 10 that has been inserted into a vertebral body 170 to provide access to the vertebral body 170 in accordance with one embodiment of the present invention. In an embodiment, the cannula assem-

bly 10 may be inserted into the vertebral body 170 through a pedicle 180. In an embodiment (not illustrated), the cannula assembly 10 is not inserted through the pedicle 180. In the illustrated embodiment, the cannula assembly 10 includes a cannula 20 having a proximal end 30 and a distal end 40 extending into the vertebral body 170. As illustrated, cannula 20 may include an inner lumen 190 configured to allow passage of various instruments and materials into the vertebral body 170. The cannula assembly 10 further may include a cannula hub 200 disposed on the proximal end 30 of the cannula 20.

[0042] Embodiments of the present technique for treating vertebral fractures may further include creating a channel in the vertebral body 170. FIG. 8 illustrates a drill 210 that may be used to create the channel in the vertebral body 170 in accordance with one embodiment of the present invention. In the illustrated embodiment, the drill 210 comprises a shaft 220 having a proximal end 230 and a distal end 240. A bit 250 may extend from the distal end 240 of the shaft 220. A handle 260 may be disposed on the proximal end 230 of the shaft. As illustrated by FIG. 9, the drill 210 may be used to create a channel 270 in the vertebral body 170. By way of example, the physician may insert the drill 210 through the inner lumen 190 of the cannula 20 until the bit 250 contacts bone (e.g., cancellous bone) within the vertebral body 170. The channel 270 in the vertebral body 170 may then be created by application of longitudinal forces to the drill 210 while rotating the handle 260. The drill 210 may then be removed from the cannula 20 leaving the cannula assembly 10 in place, for example, with the cannula 20 providing access to the channel 270 within the vertebral body 170.

[0043] Embodiments of the present technique for treating vertebral fractures may further include creating a cavity in a vertebral body 170. FIG. 10 illustrates creation of a cavity in vertebral body 170 with a balloon assembly 280 in accordance with one embodiment of the present invention. As illustrated, cannula assembly 10 has been inserted into the vertebral body 170 with the cannula 20 providing access into the vertebral body 170. To create the cavity, balloon assembly 280 may be inserted into the previously created channel 270 (illustrated on FIG. 9) in the vertebral body 170 through the inner lumen 190 of the cannula 20. In certain embodiments, the balloon assembly 280 may be an inflatable bone tamp. In the illustrated embodiment, the balloon assembly 280 includes a catheter 290 having a proximal end 300 and a distal end 310. A balloon 320 may be attached to the distal end 310 of the catheter 290. While FIG. 10 illustrates the balloon 320 in an expanded configuration, it should be understood that the balloon 320 should be inserted into the vertebral body 170 in a deflated state. The balloon 320 used to create the cavity may include any of a variety of different balloons suitable for use in medical procedures. Examples of suitable balloons include those commonly used in kyphoplasty, including those comprising plastics, composite materials, polyethylene, mylar, rubber, polyurethane, or any other suitable material. As illustrated, the balloon assembly 280 may further include an inner lumen 340 disposed within the catheter 290. As illustrated, the inner catheter 330 has an inner lumen 340 with an exit port 350, for example, that extends beyond the balloon 320.

[0044] As illustrated by FIG. 10, the balloon 320 may be inflated, for example, to compact the cancellous bone 360 in the interior portion of the vertebral body 170 enlarging the channel (illustrated on FIG. 9) to create a cavity within the vertebral body 170. In addition to creation of the cavity, the

balloon 320 may also, for example, force apart the compact bone 370, restoring height to the vertebral body 170. After cavity creation, the balloon 320 may be deflated and removed from the vertebral body 170.

[0045] While FIG. 10 illustrates the use of the balloon assembly 280 for creation of the cavity in the vertebral body 170, those of ordinary skill in the art will appreciate that other suitable techniques may also be used for creation of the cavity. By way of example, an expandable jack or other suitable mechanical device may be used to create the cavity in the vertebral body 170. FIG. 11 illustrates a mechanical device 380 that may be used to create the cavity in accordance with one embodiment of the present invention. In an embodiment, the mechanical device 380 may be inserted through the cannula assembly 10 and into the vertebral body 170. The mechanical device 380 may then be activated to create the cavity.

[0046] FIG. 12 illustrates a cavity 390 that has been created in the vertebral body 170 in accordance with one embodiment of the present invention. In accordance with present embodiments, the cavity 390 may be formed using an inflatable balloon, a mechanical device, or a combination of both. As illustrated, the cannula 20 of the cannula assembly 10 should extend into the cavity 390, providing access to the cavity 390. While not illustrated, embodiments of the present invention further may include coating the wall of the cavity 390 with a bone growing agent.

[0047] In accordance with embodiments of the present invention, a filler material may be introduced into the cavity 390, for example, to stabilize a fracture in the vertebral body 170. However, prior to insertion of the filler material, embodiments of the present technique further may include inserting a containment jacket into the cavity 390 in the vertebral body 170. The containment jacket may be employed to contain the filler material (e.g., cement) introduced into the cavity 390, for example, to prevent undesirable leakage. In this manner, problems associated with leakage of the filler material from the cavity 390.

[0048] FIG. 13 illustrates a containment assembly 400 having a containment jacket 410 that may be inserted into the cavity. As illustrated, the containment assembly 400 comprises a tubular member 420 (e.g., a cannula) having a proximal end 430 and a distal end 440. The tubular member 420 may be configured to allow passage of various instruments and materials into a vertebral body. The containment jacket 410 may be disposed on the distal end 440 of the tubular member 420. In an embodiment, the containment jacket 410 is impermeable, e.g., to the filler material. As illustrated, a hub 450 may be disposed on the proximal end 430 of the tubular member 420. The hub 450 may allow connection of the containment assembly 400 to other devices that may be used in a medical procedure. A guide wire 460 (e.g., a K-wire) may be disposed through the tubular member 430. As illustrated, the guide wire 460 may extend into the proximal end 430 of the tubular member 420 and out from the distal end 440 of the tubular member 420. In an embodiment, the containment jacket 410 is disposed on the portion of the guide wire 460 extending from the distal end 440 of the tubular member 420. For example, the containment jacket 410 may be wrapped around the portion of the guide wire 460 extending through the distal end 440 of the tubular member 420. In this manner, the guide wire 460 may facilitate insertion of the containment jacket 410 through the cannula 20. In the illustrated embodi-

ment, a cap 470 is disposed on the end of the guide wire 460 extending from the proximal end 430 of the tubular member 420.

[0049] As illustrated by FIG. 14, the containment jacket 410 may be inserted through the inner lumen 190 of the cannula 20 and into the cavity 390 within the vertebral body 170. In an embodiment, the containment jacket 410 may be in an unfolded state when it is inserted into the cavity 390. The containment jacket 410 may be inserted by sliding the tubular member 440 with the containment jacket 410 disposed thereon through the cannula 20 of the cannula assembly 10. In an embodiment, the hub 450 on the containment assembly 400 may be coupled to the cannula hub 200 on the cannula assembly 10. Once the containment jacket 410 has been placed, the guide wire 460 (shown on FIG. 13) may be removed from the containment assembly 400, leaving the containment jacket 410 in place. The cap 470 may be used to facilitate removal of the guide wire 460.

[0050] Embodiments of the present technique for treating vertebral fractures may further include removing fluid (e.g., air) from within the containment jacket 410 that has been placed into the vertebral body 170. Any of a variety of different techniques may be used to remove air from within the containment jacket. In an embodiment, a syringe may be used to remove the air. An example of a suitable syringe includes a VacLok™ syringe. As illustrated by FIG. 15, a syringe 480 may be coupled to the hub 450 of the containment assembly 400. The plunger 490 of the syringe 480 may then be withdrawn to create a partial vacuum so that air from within the containment jacket 410 flows into the syringe 480. Accordingly, the fluid in the containment jacket 410 may be removed.

[0051] As previously mentioned, embodiments of the present invention may further include introduction of a filler material into the cavity 390. In an embodiment, the filler material may be introduced directly into the containment jacket 410 that has been placed within the cavity 390. FIGS. 16 and 17 illustrate a procedure comprising introduction of a filler material 500 into the containment jacket 410 in accordance with one embodiment of the present invention. In an alternative embodiment, a balloon assembly 280 may be used while introducing the filler material into the containment jacket 410. FIGS. 22-27 illustrate use of the balloon assembly 280 with the containment jacket 410 in accordance with one embodiment of the present invention.

[0052] FIG. 16 illustrates introduction of filler material 500 into the containment jacket 410 using a syringe-type device 510. As illustrated, plunger 520 of the syringe-type device 510 may be depressed to force filler material 500 from the body 530 of the syringe-type device 510, through the tubular member 420 of the containment assembly, and into the containment jacket 410. In an embodiment, introduction of the filler material 500 into the containment jacket 410 should expand the containment jacket 410. In some embodiments, the filler material 500 may be introduced into the containment jacket 410 until the containment jacket 410 at least partially fills the cavity 390 in the vertebral body 170. In general, the filler material 500 should exert pressure to prevent (or reduce) loss of vertebral height. It may be desirable, in certain embodiments, for the filler material 500 to exert pressure that further increases height of the vertebral body 170. In certain embodiments, the filler material 500 may exert pressure that restores some height lost after removal of the balloon 320. As illustrated, the containment jacket 410 may generally conform to the shape of the cavity 390. It may be desirable, in

certain embodiments, for the containment jacket 410 to be a complaint balloon (e.g., polyurethane, collagen, silicone) that can contain the filler material 500 to prevent leakage. The containment jacket 410 may permit interdigitation of the filler material 500 with the cancellous bone 360 while being contained within the containment jacket 410.

[0053] While FIG. 16 illustrates use of syringe-type device 510 for introduction of the filler material 500, it should be understood that other suitable devices may be used to introduce the filler material 500 into the vertebral body 170. For example, FIGS. 17-21 illustrate a needle-type device 540 that may be used to introduce the filler material 500. As illustrated, the body 550 of the needle-type device 540 comprises a hollow tube 560 having a through passageway and a stop 570 at one end. The needle-type device 540 further comprises a plunger 580 having a depression mechanism 590 and a needle 600 for insertion into the hollow tube 560. The length of the needle 600 may vary. For example, FIGS. 19 and 20 illustrate needles 600 that vary in length with the needle 600 of FIG. 19 longer in length. In an embodiment, the body 550 of the needle-type device 540 may be inserted into the tubular member 420 of the containment assembly 400. Plunger 580 may then be depressed to force the filler material 500 from the body 560 of the needle-type device 540 and into the containment jacket 410.

[0054] In addition to introducing the filler material 500 directly into the containment jacket 410 as illustrated by FIGS. 15 and 16, alternative embodiments of the present invention may utilize a balloon assembly 280 while introducing the filler material 500 into the containment jacket 410. The balloon assembly 280 may be used, for example, to maintain and/or restore vertebral height while introducing the filler material 500. FIGS. 22-27 and the accompanying description illustrate use of the balloon assembly 280 with the containment jacket 410 in accordance with one embodiment of the present invention.

[0055] FIG. 22 illustrates insertion of balloon assembly 280 into the vertebral body 170 through the containment assembly 400 and the cannula assembly 10 in accordance with one embodiment of the present invention. As illustrated, cannula assembly 10 has been inserted into the vertebral body 170 with the cannula 20 providing access into the vertebral body 170. As further illustrated, the containment jacket 410 has already been inserted into the cavity 390. In an embodiment, the containment jacket 410 may be inserted by sliding the tubular member 440 with the containment jacket 410 disposed thereon through the cannula 20 of the cannula assembly 10. In accordance with embodiments of the present invention, the balloon assembly 280 may be inserted into vertebral body 170. As illustrated, the balloon assembly 280 includes a catheter 290 having a proximal end 300 and a distal end 310. A balloon 320 may be attached to the distal end 310 of the catheter 290.

[0056] As illustrated by FIG. 22, the balloon 320 may be inserted into the containment jacket 410 through the tubular member 420 of the containment assembly 400. In an embodiment, the balloon 320 may be in a deflated state when inserted through the tubular member 420. The balloon 320 may be inserted by sliding the catheter 290 with the balloon 320 disposed on the distal end 310 thereof through the tubular member 420 of the containment assembly 400. Once the balloon 320 has been placed, the balloon assembly 280 may be coupled to the containment assembly 400. By way of example, cap 610 disposed on the catheter 290 of the

balloon assembly **280** may thread onto a luer fitting **620** on the hub **450** of the containment assembly **400**. After insertion of the balloon **320**, fluid (e.g., air) may be removed from the containment jacket **410**. The fluid may be removed, for example, in accordance with the previously discussed embodiments (FIG. **15**) for removal of fluid from the containment jacket **410**. By way of example, a syringe may be used to remove air from within the containment jacket **410**.

[0057] FIG. **23** illustrates inflation of balloon **320** after it has been inserted into the containment jacket **410** in accordance with one embodiment of the present invention. In general, inflation of the balloon **320** should provide pressure on the walls of the cavity **390** to prevent (or reduce) loss of vertebral height. It may be desirable, in certain embodiments, for expansion of the balloon **320** to further increase the height of the vertebral body **170**. In certain embodiments, inflation of the balloon **320** may restore some vertebral height lost after the cavity **390** was initially created. As illustrated, the balloon **320** generally may be enclosed within the containment jacket **410**. The volume of the balloon **320**, when inflated, generally may be smaller than the volume of the containment jacket **410**, in accordance with embodiments of the present invention. Furthermore, when inflated, the balloon **320** generally may not occupy the entire volume of the containment jacket **410**. By way of example, the balloon **320** may occupy from about 25% to about 90% by volume of the containment jacket **410**.

[0058] FIG. **24** illustrates introduction of filler material **500** into the containment jacket **410** in accordance with one embodiment of the present invention. As illustrated, the filler material **500** may be introduced into the containment jacket **410** through the inner lumen **340** of the inner catheter **330** of the balloon assembly **280**. While not illustrated on FIG. **24**, a syringe-type device **510** (shown on FIG. **16**) or a needle-type device **540** (shown on FIGS. **17-21**) may be used to introduce the filler material **500** through the balloon assembly **280**. In general, the filler material **500** may be introduced into the portion of the containment jacket **410** that is not occupied by the balloon **320**. In an embodiment, the filler material **500** may fill the portion of the containment jacket **410** that is not occupied by the balloon **320**. The containment jacket **410** may expand with the introduction of the filler material **410**. The filler material **500** may then be allowed to cure in the containment jacket **410**. In an embodiment, the filler material **500** may exert pressure to prevent (or reduce) loss of vertebral height. It may be desirable, in certain embodiments, for the filler material **500** to exert pressure that further increases height of the vertebral body **170**. As illustrated, the containment jacket **410** may generally conform to the shape of the cavity **390**. It may be desirable, in certain embodiments, for the containment jacket **410** to a complaint balloon (e.g., polyurethane) that can contain the filler material **500** to prevent leakage while permitting interdigitation of the filler material **500** with the cancellous bone **360**.

[0059] As illustrated by FIG. **25**, after the filler material **500** has been allowed to cure, the balloon assembly **280** (shown on FIG. **24**) may be removed. With removal of the balloon assembly **280** and, thus, the balloon **320** from within the containment jacket **410**, a portion of the containment jacket **410** is not occupied. This unoccupied portion of the containment jacket is represented on FIG. **25** by reference number **630**. As illustrated by FIG. **25**, an access channel to the unoccupied portion **630** is maintained by tubular member **420**

of the containment assembly **400** that is disposed within the cannula **20** of the cannula assembly **10**.

[0060] FIG. **26** illustrates introduction of an additional volume of the filler material **500** into the containment jacket **410**. As illustrated, the additional volume of the filler material **500** may be introduced through the tubular member **420** of the containment assembly **400**. The additional volume of the fill material may generally fill the unoccupied portion **630** (shown on FIG. **25**) of the containment jacket **410** so that the containment jacket **410** is filled with the filler material **500**, for example. While not illustrated on FIG. **26**, a syringe-type device **510** (shown on FIG. **16**) or a needle-type device **540** (shown on FIGS. **17-21**) may be used to introduce the additional volume of the filler material **500** through the containment assembly **400**. The additional volume of the filler material **500** may then be allowed to cure in the containment jacket **410**.

[0061] Embodiments of the present invention further may include detaching the containment jacket **410** from the containment assembly **400**. FIG. **27** illustrates removal of the containment jacket **410** in accordance with one embodiment of the present invention. As previously mentioned, the containment jacket **410** may be attached to the distal end **440** of the tubular member **420**. As illustrated, a cutting device **640** having a cutting mechanism **650** in its distal end **660** may be inserted into the tubular member **420**. The cutting device **640** may then be used to detach the containment jacket **410**, leaving the containment jacket **410** within the vertebral body **170**. In another embodiment, the containment jacket **410** is provided with a perforated line detachment mechanism so that the containment jacket **410** can be detached and maintained within the vertebral body. Once the containment jacket **410** has been detached, the containment assembly **400** and the cannula assembly **10** may be removed, leaving the containment jacket **410**. Accordingly, the containment jacket **410** containing the filler material **500** may be left within the vertebral body **170**.

[0062] FIG. **28** illustrates a containment jacket **410** within a vertebral body **170** and containing a filler material **500** in accordance with one embodiment of the present invention. In an embodiment (FIGS. **15** and **16**), the filler material **500** may be introduced directly into the containment jacket **410**. In an alternative embodiment (FIGS. **22-27**), a balloon assembly **280** may be used while introducing the filler material **500** into the containment jacket **410**. In an embodiment, the filler material **500** may exert pressure to prevent (or reduce) loss of vertebral height.

[0063] The preceding description describes the use of a filler material **500** in accordance with embodiments of the present invention. Those of ordinary skill in the art will appreciate that the filler material **500** may comprise any of a variety of materials that may be utilized to, for example, fill and stabilize the cavity **390** in the vertebral body **170**. Examples of suitable materials may include bone cements (e.g. polymethyl methacrylate), human bone graft and synthetic derived bone substitutes.

[0064] In addition, the preceding description is directed, for example, to treatment of vertebral fractures that includes a containment assembly for cement containment and/or a balloon assembly for maintaining vertebral height. It should be understood that the present technique also may be used in other suitable bone treatments were maintenance of vertebral height and/or cement containment may be desired. By way of

example, embodiments of the present invention may be used to treat tibia plateau fractures, distal radius fractures, and calcaneous fractures.

[0065] While it is apparent that the invention disclosed herein is well calculated to fulfill the objects stated above, it will be appreciated that numerous modifications and embodiments may be devised by those skilled in the art.

What is claimed is:

- 1. A method for treating a bone comprising:
 - inserting a cannula having an inner lumen into the bone;
 - creating a cavity in the bone;
 - providing a containment assembly comprising:
 - a tubular member having a proximal end and a distal end,
 - a containment jacket disposed on the distal end of the tubular member, and
 - a guide wire disposed through the tubular member with the guide extending into the containment jacket;
 - inserting the containment jacket through the inner lumen of the cannula and into the cavity; and
 - introducing a filler material into the containment jacket.
- 2. The method of claim 1 wherein the cannula is inserted through a pedicle and into the bone.
- 3. The method of claim 1 comprising:
 - inserting a needle assembly through an incision in a patient's back and into the bone;
 - disposing a guide wire through the needle assembly and into the bone;
 - removing the needle assembly; and
 - inserting the cannula over the guide wire and into the bone.
- 4. The method of claim 1 comprising inserting a drill into the bone through the inner lumen of the cannula and creating a channel in the bone.
- 5. The method of claim 1 wherein creating the cavity comprises inflating a balloon in the bone.
- 6. The method of claim 1 wherein the filler material comprises a bone cement.
- 7. The method of claim 1 comprising removing fluid from the containment jacket after insertion of the containment jacket into the cavity.
- 8. The method of claim 1 comprising:
 - inserting a balloon into the containment jacket after insertion of the containment jacket into the cavity; and
 - inflating the balloon inside the containment jacket, wherein the filler material is introduced into the containment jacket while the balloon is inflated.
- 9. The method of claim 8 comprising:
 - deflating the balloon;
 - removing the balloon from the containment jacket; and
 - introducing an additional volume of the filler material into the containment jacket after removal of the balloon.
- 10. The method of claim 1 comprising detaching the containment jacket from the tubular member.
- 11. A method for treating a vertebral fracture comprising:
 - inserting a cannula having an inner lumen into a vertebral body to provide an access channel into the vertebral body;
 - creating a channel in vertebral body;
 - inserting a device into the channel in the vertebral body;

- activating the device to enlarge the channel creating a cavity in the vertebral body and restoring height to the vertebral body;
- providing a containment assembly comprising:
 - a tubular member having a proximal end and a distal end,
 - a containment jacket disposed on the distal end of the tubular member, and
 - a guide wire disposed through the tubular member with the guide extending into the containment jacket;
- inserting the containment jacket through the inner lumen of the cannula and into the cavity; and
- removing air from the containment jacket with a syringe after insertion of the containment jacket into the cavity;
- introducing a balloon through the inner lumen of the cannula and into the containment jacket;
- inflating the balloon in the containment jacket to exert force on one or more walls of the cavity;
- introducing a bone cement into the containment jacket while the balloon is inflated in the containment jacket;
- deflating the balloon;
- removing the balloon from the containment jacket; and
- introducing an additional volume of the bone cement into the containment jacket; and
- detaching the containment jacket from the tubular member.
- 12. The method of claim 11 comprising:
 - inserting a needle assembly through an incision in a patient's back and into the vertebral body;
 - disposing a guide wire through the needle assembly and into the vertebral body;
 - removing the needle assembly; and
 - inserting the cannula over the guide wire and into the vertebral body.
- 13. The method of claim 11 wherein creating the channel in the vertebral body comprises inserting a drill into the vertebral body through the inner lumen of the cannula.
- 14. The method of claim 11 wherein activating the device comprises inflating a balloon in the channel.
- 15. The method of claim 11 wherein the bone cement exerts force on one or more walls of the cavity to prevent loss of vertebral height.
- 16. A containment assembly comprising:
 - a tubular member having a proximal end and a distal end,
 - a containment jacket disposed on the distal end of the tubular member, and
 - a guide wire disposed through the tubular member with the guide wire extending into the containment jacket;
- 17. The containment assembly of claim 16 wherein the containment jacket is not permeable to bone cement.
- 18. The containment assembly of claim 16 wherein the containment jacket is wrapped around the guide wire.
- 19. The containment assembly of claim 16 wherein a cap is disposed on an end of the guide wire extending from the proximal end of the tubular member.
- 20. The containment assembly of claim 16 wherein a hub having a luer fitting is disposed on the proximal end of the tubular member.

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